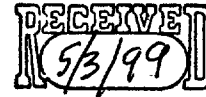




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April 26, 1999



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect. As part of a healthy diet, the daily value for folic acid intake is 400 mcg. daily.*
- (2) Folic acid maintains a healthy heart. The amino acid, homocysteine, has been shown to play a significant role in heart health. Folic acid works to reduce levels of homocysteine in the blood to sustain more acceptable levels.*
- (3) Folic acid helps maintain the healthy structure and function of DNA and cells.*
- (4) These vitamin complexes taken together work to mature and strengthen red blood cells. Another function of these vitamin complexes is in the process of DNA formation and the replication of genetic material.*

These statements are made for a dietary supplement containing a proprietary blend of carrot (root), calcium lactate, porcine stomach parenchyma, defatted wheat (germ), bovine spleen, ovine spleen, bovine adrenal Cytosol™ extract, oat flour, and ascorbic acid. Other ingredients include honey, cellulose, folic acid, and cyanocobalamin. The name of the product is Folic Acid-B₁₂.

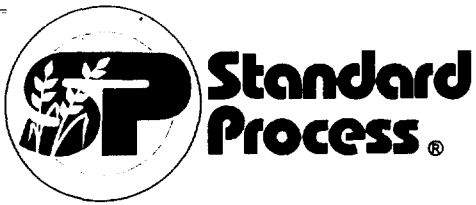
97S-0162

Also see docket 97S-0163

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LET3625





The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

